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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/844,816	04/30/2001	Paul F. Corey	MSE #2609	3320

7590 10/02/2002

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EXAMINER

GUO, LYNDA T

ART UNIT

PAPER NUMBER

1627

DATE MAILED: 10/02/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/844,816	COREY ET AL.
	Examiner	Art Unit
	Lynda T Guo	1627

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 30 April 2001.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) _____ is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 1-41 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

The Associate Power of Attorney (Paper No. 2) received on June 17, 2002 has been entered.

Claims 1-41 are pending in the present application and are subject to restriction and election of species requirements.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-11, drawn to a compound, classified in class 560, subclass 3.
 - II. Claims 12-28 and 34, drawn to a diagnostic device, classified in class 435, subclass 810.
 - III. Claims 29-33 and 35-36, drawn to a method of preparing a diagnostic device, classified in class 435, subclass 810.
 - IV. Claim 37, drawn to a method for detecting levels of urinary trypsin inhibitors, classified in class 435, subclass 213.
 - V. Claims 38-41, drawn to a diagnostic kit, classified in class 435, subclass 975.

The inventions are distinct, each from the other because of the following reasons:

2. The compound of Invention I and the device and kit of Inventions II and V, respectively, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a

materially different process of using that product (MPEP § 806.05(h)). In the instant case the device and kit as claimed can utilize other types of trypsin substrates, e.g. those compounds recited in the present Specification on page 2, lines 11-14.

3. The compound of Invention I and the methods of Inventions III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the compound can be used as part of a matrix of a diagnostic device or as a reagent used to detect or quantify trypsin inhibitors in various assays.

4. The method of Invention III and the device and kit of Inventions II and V, respectively, are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, “There are many possible ways to prepare such a diagnostic device” as recited in the present Specification on pages 21-22.

5. The method of Invention IV and the device and kit of Inventions II and V, respectively, are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different

apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process as claimed can be practiced manually.

6. The methods Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different resulting products or effects. Invention III results in a diagnostic device whereas Invention IV results in the detection of urinary trypsin inhibitors.

7. Inventions II and V are different and patentably distinct apparatus because they involve different method steps, starting materials, reagents, and/or reaction conditions and/or produce different products or results. For example, the diagnostic device of Invention II involves the use of a matrix and the diagnostic kit of Invention V is not disclosed as comprising of a matrix. Furthermore, the kit of Invention V is used for determining the presence of urinary trypsin inhibitor whereas the utility of the device of Invention II is not specified in the claims.

8. Because these inventions are distinct for the reasons given above and

- have acquired a separate status in the art as shown by their different classification;
- have different and separately burdensome: manual and/or computer: structure, name and bibliographical searches; and
- have divergent subject matter,
restriction for examination purposes as indicated is proper.

Election of Species

9. This application contains claims directed to patentably distinct species of the claimed inventions:

A. If applicant elects Invention I or II, applicant is required to elect a species for each of the following 1-3.

1. Species for R¹ group, (e.g. acyl, arene sulfonyl, carbamoyl derivatives, t-butylloxycarbonyl and derivatives, benzyloxycarbonyl and derivatives, benzoyl and derivatives, OR benzene sulfonyl and derivatives, from Claims 2-3 OR 13-14).

2. Species for R² group, (e.g. nitro, arene sulfonyl, carbamoyl, acyl, benzene sulfonyl and derivatives, tosyl, carbobenzylxy and derivatives OR benzoyl and derivatives, from Claims 4-5 OR 15-16).

3. Species for R³ group, (e.g. heterocyclic aromatic moiety or carbocyclic and further selecting from the following: phenylpyrrole and derivatives, coumarin and derivatives, phenylthiophene and derivatives, indole and derivatives OR 2-phenyl-5H-thiazol and derivatives, from Claims 6, 8, 10, 17, 19 and 21).

An ultimate species for the compound of Formula (I) with complete chemical structures, including 1-3 above should be included.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

10. A telephone call was made to Elizabeth A. Levy on 30 September 2002 to request an oral election to the above restriction requirement, but did not result in an election being made. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynda T Guo whose telephone number is (703) 605-1200. The examiner can normally be reached on Mon - Fri (8:00am - 4:30pm).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J Wang can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Lynda Guo
Lynda T Guo
Patent Examiner
September 30, 2002

R. Gitomer
RALPH GITOMER
PRIMARY EXAMINER
GROUP 1200